

SOP FOR ANNUAL PRODUCT REVIEW

1. Purpose

- 1.1. The purpose of this document is to describe the procedure for annual review of products manufactured during a year.

2. Scope:

- 2.1. It is applicable to Quality Assurance Department.

3. Responsibility:

- 3.1. Quality Assurance Manager

4. Procedure:

- 4.1. Annual product review shall be conducted each year in the month of January.
- 4.2. Product review shall be based on following critical parameters of product batches:
 - ☐ Assay
 - ☐ PH
- 4.3. Review shall be done for all batches of each product manufactured during a year.
- 4.4. Annual Product Review (APR) report shall be generated after completion of product batch data and signed by concerned authorized personnel.
- 4.5. Recommendations on deviations shall be forwarded to production department for necessary action.

5. List of Recipients:

- 5.1. Quality Assurance Manager

6. Attached Forms/ Annexures:

- 6.1. Annual Product Review (APR) format

Annual Product Review Sop

Michael Rajnik

A red circular graphic with a gradient, appearing as a partial circle or a stylized arrow pointing to the right, located to the right of the name bar.

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